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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,355	05/12/2008	Lawrence Solomon	SLP-054	2979

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EXAMINER	
LOVE, TREVOR M	
ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,355	SOLOMON ET AL.	
	Examiner	Art Unit	
	TREVOR M. LOVE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :05/18/2007, 05/18/2007, 07/30/2008.

DETAILED ACTION

Claims 1-52 are pending and are currently under consideration.

Election/Restrictions

Upon careful consideration, the requirement for species election has been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-7, 12, 45, and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131

USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, **instant claims 1, 7, and 45** recite the broad recitation "greater than 50%", and the claim also recites "preferably greater than 70%" which is the narrower statement of the range/limitation.

Instant claims 5-6 recite the limitation of the second layer comprising an outer and inner layer (respectively) which comprise a therapeutically effective quantity of any drug. Claim 1 recites the limitation that the outer and inner layers cannot comprise a therapeutically effective quantity of any drug.

Instant claim 7 recites the limitation that the third segment is a height greater than the height of the first and third segments combined. This is not possible. Appropriate correction is required.

Instant claim 48 recites the limitation "the D/d ration". There is insufficient antecedent basis for this limitation in the claim. Furthermore, the terminology is unclear for failing to establish the metes and bounds of claim 48. Claim 48, or the rest of the disclosure, fails to clearly distinguish what exactly the D/d ration is referring to.

Claim Objections

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 recites the limitation of the "first segment comprising a pharmaceutically effective quantity of the

pharmaceutical agent", however, claim 1, the independent claim from which claim 2 depends, recites the same limitation in the third line of the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11, 13-34, 39-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lieberman (Pharmaceutical Dosage Forms – tablets, 1990) in view Geller (U.S. Patent number 3,927,194).

Lieberman, in section "IV. Layer Tablets" first paragraph, discloses layered tablets wherein the granulation layers are "sandwiched" on top of each other, and the edges are exposed, this reads on **instant claim 25**. Said layered tablets are disclosed as 2 or 3 layers of granulation compressed together wherein said layers can have different colorin to allow for unique tablet identification, this reads on **instant claim 19**. Lieberman teaches that layered dosage forms have the advantage of being able to separate two incompatible substances with an inert barrier, or instead of modifying the active ingredient, they can be used to modify the release profile, each layer can comprise components that determine immediate, intermediate, or slow release of the active, this, in combination with Geller, reads on **instant claims 4, 8, 22, and 46-48**. Furthermore, Lieberman discloses that the layered tablet method allows for the weight of each layer to be accurately modified, this would also allow for the thickness of the individual layers to be regulated and modified. The multilayer tablets are also disclosed as being capable of having "distinctive markings" impressed on the surface. Lieberman, in the section discussing the "Properties of Tablets" discloses under point "4" that tablets can contain markings. Said markings may appear as a score or crease across the face, which is intended to permit breaking the tablet into equal parts for administration. Lieberman, however, states that substantial variation can occur in manually broken tablets.

Lieberman fails to directly envisage that the score on the multilayer tablet extends at least 70% of the distance of the first segment of said multilayer tablet.

Geller teaches a tablet for breaking into smaller dosages which is scored sufficiently to form a groove which is 1/3 to 2/3 the depth of the total tablet thickness (see claim 1), this can be greater than 50%, and therefore reads on **instant claims 1-3, 5-7, 14, 24, 32, 45, and 49**. This groove being designed to facilitate separation into subdivisions containing substantially equal amounts of pharmaceutically active ingredients (see claim 1 and figures 1, 2, 4, and 5), this reads on **instant claims 13, 17, 20, 26, 42, and 44**.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the groove of Geller in the tablets of Lieberman. One would have been motivated to do so with a reasonable expectation of success since both Lieberman and Geller teach that tablets can be scored in order to facilitate breaking the tablet into equal parts for administration.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have all three layers be directly atop one another. One would have been motivated to do so since Lieberman teaches a two or three layer composition wherein the components have the appearance of a sandwich because the edges of each layer are exposed (see page 274, section IV first paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the contents of the different layers. One would have been motivated to use different actives in the different layers since Lieberman teaches

one motivation for layering is the separation of incompatible layers, which would obviously contain different substances, at least three to achieve effective separation (see page 274, section IV, first paragraph). In the same paragraph Lieberman teaches that another motivation for layering is varying the speed of release of the different coatings. Lieberman directly teaches three coatings, all with different release rates: immediate, slow release, and intermediate release. Lieberman also teaches that the weights of the layers can be varied. These teachings of Lieberman read on tablets with varing concentrations with three different actives (or non-actives) with three different release rates, tablets with three of the same actives with different (or the same) release rates (such as **instant claim 9 and 15-16**), or combinations thereof (such as **instant claim 10, 11, 18, and 28-29**).

With regards to the difference between the 70% of the instant claims and the 66.66% of Geller, MPEP 2144.05 states:

> "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)

Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to try a score that was at least 70%.

With regards to **instant claims 21, 23, 27, 30, 31, 33, 34, 39-41, 43, and 50**, the thickness of the layers is not specified, however, the ability to modify the weight of the different layers is taught Lieberman. It would have been obvious to one of ordinary skill

in the art to optimize the thickness of each layer; this is directly taught by Lieberman (see page 274, section IV, first paragraph). One would have been motivated to do so to minimize the amount of the crucial dosage layers that are involved in the breaking of the tablet, leaving non-crucial layers, such as layers 2 or 3 to be broken through. This reduces the variability in the concentration of the components of the top layer. There would be a reasonable expectation of success in varying the thickness, which would vary the amount of each layer affected by the score, since Lieberman directly teaches that the layers can be varied.

With regards to whether the amount of an active present is therapeutically effective is dependent on the condition being treated not the size of the tablet. It is therefore inherent that the amounts and percentages described by Lieberman would inherently be therapeutic in some scenarios.

Claims 35-38 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lieberman (Pharmaceutical Dosage Forms – tablets, 1990) and Geller (U.S. Patent number 3,927,194) in view of Löfroth et al (U.S. Patent number 6,827,947).

The teachings of Lieberman and Geller are set forth above.

Lieberman and Geller fail to directly disclose that the composition is placed in a sachet. They further fail to teach that the active is metoprolol, and that the active is treating a cardiovascular condition, psychiatric condition, diabetes, thyroid disorder, pain, or thrombotic disorder.

Löfroth teaches an oral dosage form that has modified release properties, wherein the dose size is adaptable, and the tablet is divisible, this reads on **instant claim 37**. Löfroth teaches that the active is preferably metoprolol, which aids in the treatment of cardiovascular disease (see column 1, lines 44-52 and column 6, lines 37-56), this reads on **instant claim 38 and 51**. Said composition is taught to be coated and then placed into a sachet (see column 5, lines 7-11), this reads on **instant claims 35-36**.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the metoprolol of Löfroth in the invention of Lieberman and Geller. One would have been motivated to do so since Löfroth teaches that metoprolol is known to be successful in divisible tablets that have modified release profiles. There would be a reasonable expectation of success in the combination since Löfroth teaches that metoprolol is known to work under in tablets that are to be divided and have modified release profiles.

With regards to **instant claim 52**, the location of the actives, and the amounts thereof, are taught by Lieberman as being readily modifiable. Furthermore, Lieberman teaches that drugs can be separated to allow for different rates of release, therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have two layers that comprised metoprolol with different release rates for each layer.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/598,344. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The copending application teaches in copending claim 1 an immediate release pharmaceutical tablet having a first segment which contains a drug, a score, and a second segment, wherein either said second segment does not contain a drug or said score extends at least 70%, this reads on **instant claim 1** since instant claim 1 does not specify how the first segment is altered to achieve said release, and therefore, making a composition be immediate release could be altering the release.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed. All claims rejected. No claims objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL
/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
January 20, 2009